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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,149	04/16/2004	Michael A. Spohn	CV/04-002	8770

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EXAMINER

GILBERT, ANDREW M

ART UNIT	PAPER NUMBER
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3767

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06/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/826,149	Applicant(s) SPOHN ET AL.	
	Examiner ANDREW M. GILBERT	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27,40-42,55-60 and 70-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27,40-42,55-60 and 70-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/27/2008; 5/30/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on 2/27/2008.
2. In the reply the Applicant amended claims 27, 42, 60 and cancelled claims 1-26, 28-39, 43-54, 61-69.
3. Thus, claims 27, 40-42, 55-60, 70-75.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 5/30/08, 2/27/08 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

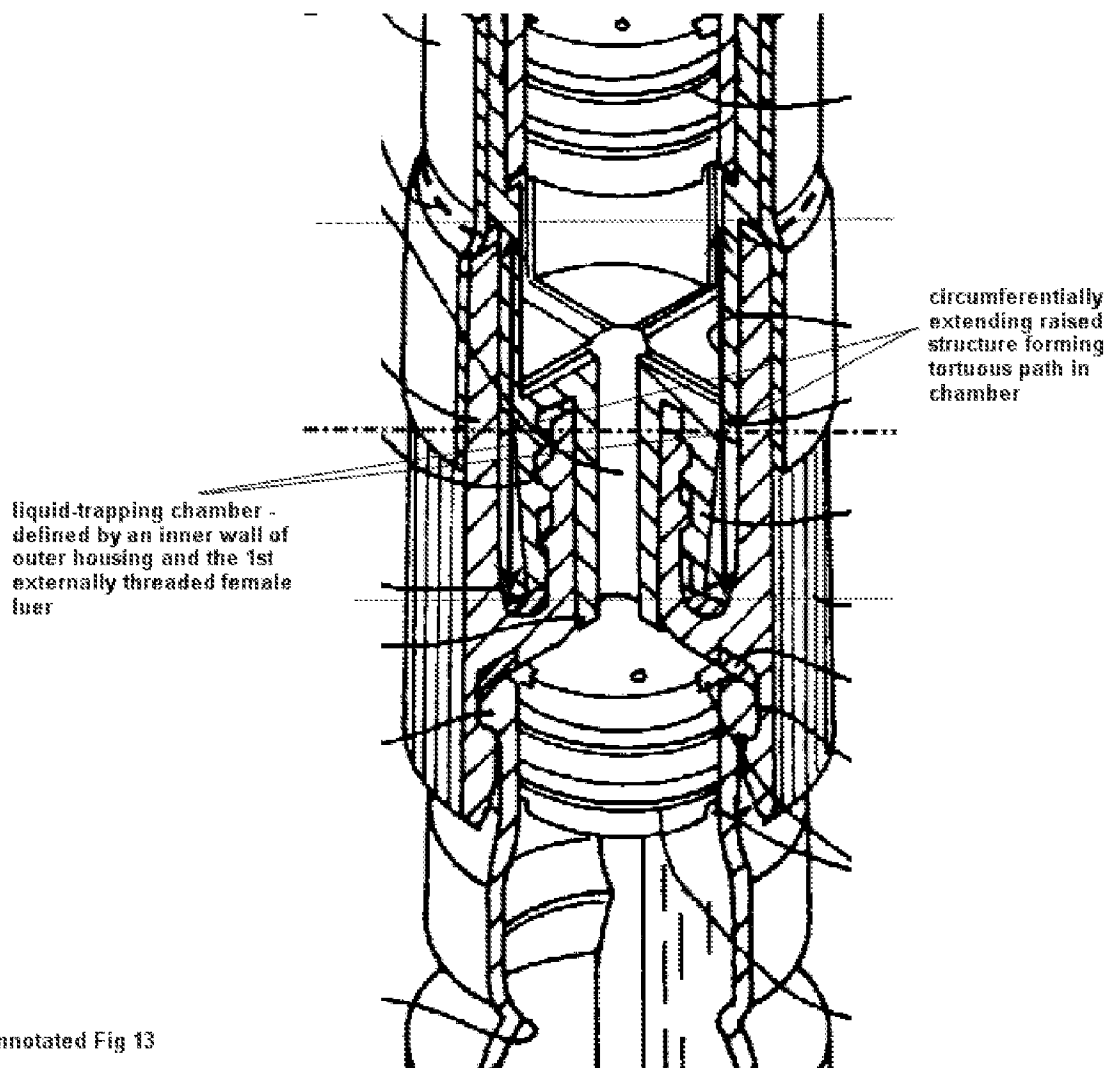
6. Claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by Holm (5746979). Holm discloses a connector, comprising: a first connector member (3; Fig 1-4) comprising an outer housing and a first externally threaded female luer member (9) coaxially disposed in and recessed within the outer housing and separated therefrom by an annular cavity (1 or 23; the Examiner notes that the Applicant has not structurally defined the annular cavity to preclude either of 1 or 23 from reading on the claim limitations; the Examiner strongly recommends further structurally defining the annular

cavity); and a second connector member (2) comprising a male luer disposed in and recessed within an internally-threaded second member (11), the internally-threaded second member comprising at least one circumferentially-extending raised structure (12) on an external surface thereof, the at least one raised structure extending into a liquid-trapping chamber (chamber formed by walls of 5, 6, 10, 14; wherein the Examiner notes that 'extending into' is synonymous with reaching into or across the chamber; wherein the chamber itself has not been structurally defined in the claim limitations; and that "trapping" is defined as something by which something else is stopped or caught - in its broadest sense, "liquid-trapping" does required that the liquid be stopped and caught and never release – rather, the liquid can just be arrested in motion for a period of time before being released; thus the shoulder 12 acts to arrest, stop, and catch liquid in the chamber and acts to inhibit liquid flow, in a "tortuous path" (ie a twist, bend, or turn) in the chamber by providing a shoulder than extends into the chamber and bends the path of liquid possible flowing there through. The Examiner suggests structurally defining the liquid-trapping chamber, structure of the tortuous path, and or including recitations that the liquid capturing chamber is also liquid tight, non-leaking, and/or with no fluid flow there through) defined by an inner wall of the outer housing and the first externally-threaded female luer member (8,9 Figs 1-4) and further defining a tortuous path with the inner wall of the outer housing for inhibiting liquid flow from the liquid-trapping chamber between the outer housing and the internally-threaded second member when the first connector member is connected to the second connector member (Figs 1-4); wherein the first externally-threaded female luer member and the

internally-threaded second member cooperate to securely and releasably connect the first connector member to the second connector member (Figs 1-4), and wherein the internally-threaded second member is received in the outer housing of the first connector member when the first connector member is connected to the second connector member (Figs 1-4).

7. Claims 27, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Morimoto et al (6224568). Morimoto et al discloses a connector (13), comprising: a first connector member (41) comprising an outer housing and a first externally threaded female luer member (43) coaxially disposed in and recessed within the outer housing and separated therefrom by an annular cavity (41; Fig 13); and a second connector member (4) comprising a male luer disposed in and recessed within an internally-threaded second member (4a), the internally-threaded second member comprising at least one circumferentially-extending raised structure (4) on an external surface thereof, the at least one raised structure extending into a liquid-trapping chamber (chamber formed by walls of 4a, 41 see annotated figure below; wherein the Examiner notes that 'extending into' is synonymous with reaching into or across the chamber; and wherein the chamber itself has not been structurally defined in the claim limitations); defined by an inner wall of the outer housing and the first externally-threaded female luer member (41, 4a) and further defining a tortuous path (wherein a "tortuous path" (ie a twist, bend, or turn) in the chamber by providing a extending annular shoulder than extends into the chamber and prevents the path of liquid possible flowing there through. The Examiner

suggests structurally defining the liquid-trapping chamber, structure of the tortuous path, and or including recitations that the liquid capturing chamber is also liquid tight, non-leaking, and/or with no fluid flow there through with the inner wall of the outer housing for inhibiting liquid flow from the liquid-trapping chamber; the Examiner notes that because the applicant has not structurally defined the chamber the Examiner can claim that the external flange 4 is not a sealing engagement of the chamber and rather is a circumferentially extending raised structure that extends into the chamber and forms a tortuous path for fluid flow therethrough) between the outer housing and the internally-threaded second member when the first connector member is connected to the second connector member (Fig 13); wherein the first externally-threaded female luer member and the internally-threaded second member cooperate to securely and releasably connect the first connector member to the second connector member (Figs 13), and wherein the internally-threaded second member is received in the outer housing of the first connector member when the first connector member is connected to the second connector member (Fig 13); wherein the reservoir and syringe barrel act as a fluid path set for use in a fluid delivery system via the syringe and comprises a first section (5) and a second section (1).



Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holm in view of Raines et al (561268). Holm discloses the invention substantially as

claimed except for expressly disclosing a cap having a groove associated with a raised rib of at least one of the first and second connector members. Raines et al teaches that it is known to have a cap with a groove (21, 66, 16) for a connector member for the purpose of protecting the infusion port and connector prior to use. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Holm with the protective cap as taught by Raines et al for the purpose of protecting the infusion port and connector prior to use.

10. Claims 40-41, 55-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morimoto et al in view of Raines et al (561268). Morimoto et al discloses the invention substantially as claimed except for expressly disclosing a cap having a groove associated with a raised rib of at least one of the first and second connector members. Raines et al teaches that it is known to have a cap with a groove (21, 66, 16) for a connector member for the purpose of protecting the infusion port and connector prior to use. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Morimoto et al with the protective cap as taught by Raines et al for the purpose of protecting the infusion port and connector prior to use.

11. Claims 27, 42, 57-60, 72-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trombley, III et al (6096011) in view of Morimoto et al. Trombley, III et al discloses an injector system comprising: a source of injection fluid (505); a pump device (350); a fluid path set (Fig 6A-B) disposed between the source of injection fluid

and the pump device, and comprising a first section (420) and a second section (510); and at least one connector (Fig 2-5) providing the removable fluid communication between the first section and the second section, the connector comprising: a first connector member (155) associated with one of the first section and the second section and comprising an outer housing (172) and a first threaded member (172) disposed in the outer housing; and a second connector member (175) associated with the other of the first section and the second section and comprising a second threaded member (192); wherein the first threaded member and second threaded member cooperate to securely and releasably connect the first member to the second member to establish the removable fluid communication between the first section and the second section (Figs 1-6b; col 5, lns 38-45), and wherein the second threaded member is received in the outer housing of the first connector member when the first connector member is connected to the second connector member (Fig 5); as to claims 57-59 and 73-75, see (Fig 6A, B; wherein the drip chamber has a projection, or spike 520; 400; col 6, lns 18-34; and 194 and proximal edge portion of 155 (ie corners closest to reference number 166) in Fig 4).

12. However, Trombley, III et al does not expressly disclosing a connector having a first connector member having an first threaded member separated therefrom by an annular cavity.

13. Morimoto et al teaches that it is known to have a connector (13) having a first connector member (41) having a first threaded member (41, 43) separated therefrom by an annular cavity (41) for the purpose of providing a shield between the sealing

members (14, 41) of first and second connectors and the external environment helping to maintain sterility during storage or use. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the first connector as taught by Trombley, III et al with the first connector being separated therefrom by an annular cavity as taught by Morimoto et al for the purpose of providing a shield between the sealing members (14, 41) of first and second connectors and the external environment helping to maintain sterility during storage or use. Also, see above discussion of Morimoto et al.

14. Claims 40-41, 55-56, and 70-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trombley, III et al in view of Morimoto et al in view of Raines et al. Trombley, III et al and Morimoto et al disclose the invention substantially as claimed except for expressly disclosing a cap having a groove associated with a raised rib of at least one of the first and second connector members. Raines et al teaches that it is known to have a cap with a groove (21, 66, 16) for a connector member for the purpose of protecting the infusion port and connector prior to use. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Trombley, III et al and Morimoto et al with the protective cap as taught by Raines et al for the purpose of protecting the infusion port and connector prior to use.

Response to Arguments

15. Applicant's arguments filed 2/27/2008 have been fully considered but they are not persuasive. See discussions above in discussion of references.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767